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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,795	11/23/2001	George Jackowski	2132.105	5610

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EXAMINER	
DAVIS, DEBORAH A	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/991,795	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Deborah A. Davis	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response to the Office Action mailed on July 19, 2005 has been acknowledged. Currently, claim 1 is under consideration for examination. Claims 39-46 are withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/439,587. The instant claim 1 of George Jackowski et al discloses an isolated biopolymer marker consisting of SEQ ID NO: 1. (see claim 1 and sequence listing).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, credible or a well-established utility.

Applicant has identified bands 2 and 3 to be indicative of SEQ ID NO:1 in Figure 1 of the drawings. Applicant has disclosed in the remarks/arguments that the biopolymer marker of band 2 is evident in the 3 normal and 1 disease control samples but not evident in 4 of the disease samples. Applicant has disclosed that band 3 is evident in all 5 diseased samples, but not evident in the normal controls samples. However, in Figure I of the drawings reveal that band 3 is not evident in Diabetes type I, and one disease sample of Insulin Resistance. Figure 1 of the instant drawings reveal that band 3 is evident in one disease sample of Insulin Resistance and two normal samples. Band 2 in Figure 1 of the drawings is not evident in any normal or disease samples. Therefore the differential expression of SEQ ID NO: 1 is not evident and the data results are ambiguous. The examiner maintains the correlation with respect to a link to insulin is not exemplified or disclosed in the specification in a way that one of ordinary skill in the art could distinguish the differential expression in an insulin resistance subject versus that of a normal subject. Therefore, one of ordinary skill in the art would not be able to distinguish a credible and specific or well establish utility that SEQ ID NO: 1 is linked to insulin resistance. Although the MPEP does not require examples, however, the teaching provided must be substantial enough to enable one of

ordinary skill in the art to ascertain the credibility of the evidence presented. Accordingly, the specification does not identify a substantial, credible or well-established utility for sequence consisting of SEQ ID NO: 1.

Claim 1 is also rejected under 35 USC 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not known how to use the claimed invention.

Response to Arguments

Applicant's arguments filed July 19, 2005 have been fully considered but they are not persuasive.

Applicant argues that there is a well-established, credible and substantial utility for SEQ ID NO:1 because comparing Bands 2 and 3 as shown in Figure 1, it is evident that the claimed biopolymer marker is differentially expressed between insulin resistant/diabetes and normal controls. The differential expression of bands 2 and 3 indicate that there may be a link to insulin resistance and/or diabetes. Applicant further argues that the search for specific biomarkers found to be differentially expressed between disease and normal are frequently identified as potential targets for diagnostics and/or therapeutics.

In response, these arguments are noted but not found to be persuasive because of the ambiguity of drawings. As stated above, Figure I of the drawings reveal that band 3 is not evident in Diabetes type I, and one disease sample of Insulin Resistance.

Figure 1 of the drawings reveals that band 3 is evident in one disease sample of Insulin Resistance and two normal samples. Band 2 in Figure 1 of the drawings is not evident in any normal or disease samples. Therefore the differential expression of SEQ ID NO: 1 is not evident and the data results are ambiguous.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McKelvey Terry can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. A. D.

Deborah A. Davis
Patent Examiner
Art Unit 1655
May 2007

Terry a McKelvey

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER